

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Furosemide Inovamed

Tablets

Active ingredient:

Each tablet contains:
Furosemide 40 mg

For information regarding inactive ingredients and allergens in the preparation see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist. This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

Therapeutic activity

Diuretic for the treatment of pulmonary edema, edema that accompanies congestive heart failure, liver cirrhosis, kidney disease and for the treatment of hypertension.

Therapeutic class: diuretics.

These medicines are given for treatment of edema, a condition in which there is too much water in your body. This condition can occur due to a problem in the heart, lungs, kidneys, liver, blood vessels or high blood pressure.

Furosemide Inovamed helps the kidneys to get rid of the excess water that is not needed in the body.

2. Before using the medicine

- Do not use this medicine if:**
- You are sensitive (allergic) to the active ingredient, furosemide, to other sulfonamides or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
 - You suffer from severe kidney impairment which prevents them from functioning properly and producing urine.
 - You suffer from kidney failure due to medicines or chemicals that tend to cause kidney damage or liver damage or if you have kidney failure as a result of liver disorders.
 - You have very low levels of potassium, sodium or other electrolytes in the blood or low blood volume (the doctor will be able to advise you).
 - You are dehydrated.
 - You have low blood pressure.
 - You are taking potassium supplements or potassium-sparing diuretics for treatment of high blood pressure (such as amiloride or spironolactone).
 - You have altered levels of consciousness and coma as a result of **liver cirrhosis** (fatigue, weakness, water retention, nausea or vomiting, weight loss or decreased appetite, yellowing of the skin or eyes, itch) or as a result of **liver encephalopathy** (confusion, altered levels of consciousness and coma as a result of liver failure).
 - You have Addison's disease (low levels of corticosteroid hormones secreted).
 - You have digitalis poisoning (nausea or vomiting, high levels of potassium in the blood, slow, fast or irregular heartbeat).
 - You are breastfeeding.

Special warnings regarding the use of the medicine

Before treatment with Furosemide Inovamed, tell the doctor if:

- You suffer from low blood volume (hypovolemia).
- You are at risk of developing low blood pressure or in case of premature infants as they may be more prone to developing kidney stones.
- You have liver congestion (slow blood flow through the blood vessels) or other liver problems.
- You have kidney problems or you have low levels of proteins in the blood (hypoproteinemia) as a result of kidney impairment.
- You have abnormal blood problems.
- You have or may have diabetes. If you are taking insulin, the doctor may need to adjust your insulin dosage.
- You are elderly, if you are taking other medicines which may lower blood pressure and if you have other medical conditions that put you at risk of a drop in blood pressure.
- You suffer from low blood pressure or feel dizzy when standing up.
- You feel dizzy or dehydrated. This can happen if you have lost a large amount of water due to vomiting, diarrhea or passing urine very frequently. It can also happen if you are finding it hard to drink or eat.
- You have low blood levels of essential minerals like sodium or potassium or you have acid-base imbalance in the body identified in blood tests.
- You suffer from prostate problems, i.e. enlarged prostate gland (men only) or you have difficulty passing urine.
- You are about to undergo a glucose test.
- You have gout (characterized by painful joints due to increased levels of uric acid).
- You are about to undergo blood or urine tests.
- You have increased levels of calcium or low levels of magnesium in the blood; careful monitoring of fluids and electrolyte levels is recommended.
- You are already being treated with medicines such as non-steroidal anti-inflammatory drugs (NSAIDs – for treatment of inflammation and pain) or ACE inhibitors (medicines used for lowering blood pressure).

Tests and follow-up

While you are taking this medicine, the doctor may monitor your condition and refer you to blood tests.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Medicines called ACE inhibitors (such as ramipril, enalapril, perindopril) or angiotensin II receptor blockers (such as losartan, candesartan, irbesartan). Your doctor may need to change your dose of the medicine or ask you to stop taking it.
- Alikiren – for treatment of hypertension.
- Medicines for lowering blood pressure such as renin inhibitors, alpha blockers (such as prazosin), diuretics (such as amiloride, spironolactone), phenothiazines (such as promethazine).
- Medicines for treatment of heart rhythm disorders from the beta blockers group (such as sotalol, atenolol, propranolol).
- Medicines such as tricyclic antidepressants (such as amitriptyline), monoamine oxidase inhibitors (MAOIs) (such as selegiline) or hypnotic and anti-anxiety medicines (such as barbiturates).
- Medicines for lowering blood pressure or cardiac problems (irregular heart rate) such as calcium channel blockers, beta blockers, clonidine, moxonidine, sodium nitroprusside, amiodarone, disopyramide, flecainide, minoxidil, lidocaine, hydralazine, diazoxide, methyldopa.
- Digoxin which is used for treatment of heart failure. The doctor may need to change the dosage of the medicine.
- Lithium – for treatment of mental diseases.
- Sucralfate – this medicine may decrease the absorption of Furosemide Inovamed.
- Cholestyramine or colestipol – for treatment of high cholesterol.
- Non-steroidal anti-inflammatory medicines (NSAIDs) – medicines for treatment of pain and inflammation (such as ibuprofen, naproxen, indomethacin, ketorolac) or salicylates (such as aspirin).
- Aminoglycoside or polymyxin antibiotics as they may be a risk of damage to the ears or kidneys (such as cefaclor, gentamicin, vancomycin).
- Amphotericin (for treatment of fungal infections).
- Medicines for treatment of epilepsy (anticonvulsants such as carbamazepine, phenytoin).
- Antifungals (risk of potassium loss or kidney damage indicated with furosemide).
- Medicines used for treatment of viral infections, such as ritonavir.
- Medicines used for treatment of inflammation, known as corticosteroids such as prednisolone, dexamethasone.
- Medicines or food products containing licorice (increased risk of potassium loss with furosemide).
- Cisplatin – for the treatment of cancer (increased risk of kidney damage with furosemide).
- Methotrexate – increased risk of furosemide toxicity.
- Levodopa – for the treatment of Parkinson's disease (increased risk of lowering blood pressure with furosemide).
- Medicines for suppression of the immune system (such as cyclosporine).
- Medicines used as muscle relaxants such as baclofen or tizanidine.
- Birth control pills or medicines containing estrogen may block the effect of furosemide if taken concomitantly.
- Medicines such as alprostadil, for treatment of erectile dysfunction (impotence).
- Theophylline for treatment of wheezing and difficulty breathing.
- Probenecid for prevention of gout.
- Medicines used for general anesthesia.
- Laxatives – used to relieve constipation.
- Medicines for diabetes (such as insulin). There may be decreased effectiveness when taking Furosemide Inovamed.
- Medicines for treatment of mental problems known as 'psychoses' such as risperidone, amisulpride, pimozide or chlorpromazine. Avoid using pimozide concomitantly with furosemide.
- Medicines for treatment of asthma when given in high doses.
- Other diuretics such as bendroflumethiazide. The doctor may need to change the dosage of your medicine.
- Potassium salts used for treatment of low potassium level in the blood.

Use of the medicine and food

The medicine may be taken with food.

Use of the medicine and alcohol consumption

You should avoid drinking alcohol while taking Furosemide Inovamed as this may cause further drop in your blood pressure.

Pregnancy and breastfeeding

Consult a doctor before taking Furosemide Inovamed if you are pregnant or breastfeeding, think you are pregnant or are planning to have a baby.

Pregnancy

Do not take Furosemide Inovamed if you are pregnant, unless you have been told otherwise by your doctor.

Breastfeeding

Do not breastfeed if you are taking Furosemide Inovamed. This is because small amounts may pass into breastmilk.

Driving and operating machinery

In some patients, Furosemide Inovamed may cause dizziness or reduce alertness, which can interfere with the ability to drive or operate machinery. If you

feel less alert than usual, do not drive or operate machinery and consult your doctor.

Important information about some of the ingredients of the medicine

Furosemide Inovamed contains lactose monohydrate, which is a type of sugar. If you have been told by the doctor that you have lactose intolerance or that you cannot digest certain sugars, consult the doctor before taking this medicine.

This medicine contains less than 1 mmol of sodium (23 mg) per tablet, and is thus considered to be sodium-free.

See also section 6 – "Additional information".

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

Dosage

The dosage and treatment regimen will be determined only by the doctor.

The doctor will adjust the dosage for each patient according to his condition and reaction.

Do not exceed the recommended dose.

Method of use

No information is available regarding crushing/chewing the tablet.

The tablet can be halved at the score line.

The tablets should be swallowed with some water.

The medicine may be taken with food.

If you accidentally took a higher dosage

If you took an overdose or if a child accidentally swallowed this medicine, refer to the doctor or to a hospital emergency room immediately and take the package of the medicine with you. Symptoms of an overdose include dehydration and changes in the levels of certain substances in the blood.

If you forgot to take the medicine

If you forgot to take this medicine at the required time, take the dose as soon as you remember and then take the next dose at the usual time. Do not take a double dose in order to compensate for the forgotten dose.

Follow the treatment as recommended by the doctor. Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine.

Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Furosemide Inovamed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Refer to a doctor or to a hospital immediately if you have any of the following serious side effects:

- Severe allergic reaction which may include itching, skin rash with severe itching and hives, fever, sensitivity to light, swelling of the face, lips, tongue or throat or difficulty breathing or swallowing.
- Blisters or skin exfoliation around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever can be a condition called toxic epidermal necrolysis.
- Blood vessel inflammation (vasculitis) which may cause rash, fever and joint or muscle pain or kidney inflammation, which may change the number of times you pass urine or you may see blood in the urine. You may have fever, feel drowsy, or notice swelling, for example, of the ankle.
- Red patches on the skin, joint pain and/or eye infection, "acute generalized exanthematous pustulosis (AGEP)" (acute febrile drug eruption), characterized by severe acute (allergic) reaction accompanied by fever and blisters on the skin/peeling of the skin and tiny spots from bleeding in the skin.
- Sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen or pain radiating to the back.
- Any unexplained bruising or bleeding, fever, sore throat, mouth ulcers. This can be a sign of low blood count, agranulocytosis.
- Abnormal blood count (white blood cell reduction) accompanied by increased susceptibility to infection.
- Aplastic anemia (a condition characterized by red blood cell reduction).
- Signs of kidney inflammation, e.g. pain in the sides, blood in the urine.
- Shock (severe drop in blood pressure, extreme pallor, restlessness, weak and fast heartbeat, clammy skin, impaired consciousness) as a result of a sudden and severe dilation of blood vessels due to allergy to certain substances.
- Psychiatric disorder.
- Changes in the liver causing yellowing of the skin or whites of the eyes.
- Blood clot (causing pain, swelling or tenderness in the legs).

Additional side effects

You should inform the doctor or pharmacist if you notice any of the following side effects:

Very common side effects – effects that occur in more than one user out of ten:

- Dehydration, altered balance of fluids and substances in the body (such as sodium, potassium, chlorine, calcium and magnesium) causing a dry mouth, weakness, tiredness or drowsiness, restlessness, convulsions, muscle pain, weakness or cramps, low blood pressure causing decreased concentration and slowed reactions, difficulty urinating, fast or irregular heartbeat, nausea and vomiting

Common side effects – effects that occur in 1-10 users out of 100:

- Low blood volume (hypovolemia)
- Increased creatinine and urea values in the blood (seen in blood tests)

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

- Changes in vision including blurry or yellow vision
- Changes in the body seen in tests such as glucose levels or levels of uric acid
- The blood levels of some fats (cholesterol and triglycerides) may increase, but usually return to normal levels within 6 months
- Gout
- Irregular heart rate
- Muscle cramps or weakness
- Changes in the amount of urine or in the need to urinate
- If you have a bladder disorder, enlarged prostate gland or ureteral stricture, production of urine may suddenly stop
- Decreased blood pressure causing impaired concentration and reactions, a feeling of light-headedness, sensations of pressure in the head, headache, dizziness, drowsiness, feeling weak, changes in vision, dry mouth and an inability to stand upright
- Sensitivity to light (photosensitivity)
- Feeling tired
- Dry mouth, thirst, bowel disorders such as diarrhea, constipation, nausea or vomiting
- Hearing problems such as 'ringing in the ears', deafness (sometimes irreversible)

Rare side effects – effects that occur in 1-10 users out of 10,000:

- An increase in certain cells in the blood (eosinophils)
- An increase in certain liver enzymes
- Feeling numbness and prickling, itching or tingling sensation in the skin
- Confusion, headache, dizziness, fatigue, general malaise, fever
- If you have a urinary tract obstruction, increased urine production may occur or worsen
- Skin rashes including itching

Very rare side effects – effects that occur in less than one user out of 10,000:

- Involuntary muscle movements
- **Side effects with unknown frequency (effects whose frequency has not yet been determined):**
- Metabolic acidosis, characterized by chest pain, irregular heartbeat, headache, feeling nausea, vomiting, abdominal pain, altered appetite and weight gain, muscle weakness, bone and joint pain
- A decrease in potassium levels in the body (potassium deficiency) characterized by muscle weakness and inability to contract one or more muscles (paralysis), increased excretion of urine and heart problems
- Various forms of skin inflammation (dermatitis) including allergic rash (urticaria), bullous lesions, erythema multiforme, purpura (bleeding under the skin), skin inflammation accompanied by peeling of the skin (exfoliative dermatitis), itch

Additional side effects in children:

- Deposits of calcium salts in the kidneys or heart defects such as patent ductus arteriosus have been reported in premature infants following treatment with furosemide
- Kidney stones in infants

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not indicated in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

• Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

• Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

• **Store the medicine in a cool and dry place, at a temperature below 25°C.**

• Do not discard medicines via wastewater or the trash. Ask your pharmacist how to destroy medicines no longer in use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, maize starch glycolate (type A), magnesium stearate.

What does the medicine look like and what are the contents of the package?

White to off-white, opaque, circular, flat beveled edge tablets debossed with "F" and "40" separated by break line on one side and plain on other side.

Package type: the medicine is supplied in a carton package containing 30 tablets in trays (blisters).

License holder and importer: Inovamed Pharma Ltd., P.O. Box 2349, Bnei Brak.

Name of the manufacturer: Aurobindo Pharma Ltd., Hyderabad, Telangana, India.

This leaflet was revised in November 2024.

Registration number of the medicine in the national drug registry of the Ministry of Health: 174-14-36620